Review Date: _____

Additional DHHS Protections for Children Involved as Subjects in Research

Checklist for Protocol # _____

The purpose of this checklist is to aid you in your evaluation of CDC research involving children. In addition to other responsibilities assigned to IRBs..., each IRB shall review and approve only research which satisfies the conditions of all applicable sections of the Federal Regulation dealing with children.

Minimal Risk

The Federal Regulations divide research into that which is minimal or not greater than minimal risk to the participant and that which is greater than minimal risk. The definition of minimal risk given in §46.102(I) reads as follows:

"Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Level of Risk for this protocol (please insert "minimal" or "greater than minimal"):

_____

An IRB can only approve research that falls into one of the following four categories (complete/check one only):

Category	46 CFR 46 Subpart "D"	Notes
Not Involving Greater than Minimal Risk 45 CFR 46.404	"...only if...IRB finds that adequate provisions...made for soliciting...assent of the children AND...	
	...the permission of their parents or guardians... (one parent may give permission)"	
Greater than Minimal Risk but...Prospect of Direct Benefit to the Individual Subjects or by a Monitoring Procedure that is Likely to Contribute to the Subject's Well-being 45 CFR 46.405	"...risk...justified by...anticipated benefit to...subjects AND...	
	...relation of... anticipated benefit to...risk is at least as favorable... as that presented by available alternative approaches; AND...	
	...adequate provisions...made for soliciting...assent of the children...AND...	
	...the permission of their parents or guardians (one parent may give permission)."	

Category	46 CFR 46 Subpart "D"	Notes
Greater than Minimal Risk and No... Direct Benefit to Individual Subjects, but Likely to Yield Generalizable Knowledge about...Subject's Disorder or Condition or...a Monitoring Procedure...Likely to Contribute to...Subject's Well-being *45 CFR 46.406*	"...risk represents a minor increase over minimal risk AND...	
	...intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in... actual or expected medical, dental, psychological, social, or educational situations; AND...	
	...intervention or procedure...likely to yield generalizable knowledge about...subjects' disorder or condition which is of vital importance for...understanding or amelioration of... subjects' disorder or condition; AND...	
	...adequate provisions are made for soliciting assent of the children AND...	
	...permission of their parents or guardians (both parents must give permission)."	
Not Otherwise Approvable which Presents...Opportunity to Understand, Prevent, or Alleviate...Serious Problem Affecting...Health or Welfare of Children *45 CFR 46.407*	*If you check this category, IRB should not approve without consulting the Human Subjects Office.*	

Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if 45 CFR 46.409 applies.